REMARKS

The issues outstanding the Office Action mailed July 25, 2007, are the objection to the specification and the rejections under 35 U.S.C. §101 and §112. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

Objection to the Specification

First, at page 3 of the Office Action, the specification is objected to as the result of "incorporation" of essential material." The "essential material" referred to at page 4 of the Office Action is the various background references discussing receptor binding assays. Such is clearly *not* essential material. It is argued, at page 4 of the Office Action that "without the data from these assays potential inoperative embodiments cannot be identified and there is no way to determine dosages without this quantitative biological." Applicants respectfully disagree.

First, the "data" from the assays is unnecessary. It is the assays, themselves, which are used in order to determine a given compound is active. However, these assays are old, and well known in the art. It is well established that a specification need not, and preferably *does not*, contain information which is well known in the art. See, for example, *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) which is cited in the MPEP in §2163, concerning adequacy of disclosure. Indeed, *Hybritech*, on analogous facts to the present situation, held that screening methods used to identify necessary characteristics including binding affinity of the monoclonal antibodies used in the invention were known in the art and that the patent need not specifically recite such screening techniques. The Court found, in such a situation, that the claims read in light of the specification apprised one of ordinary skill in the art of how to make the determination. Since calculating affinity was well known in the art at the time of filing, the specification clearly did not omit essential material. See 231 USPQ at 94.

Accordingly, it is clear that the well known assays disclosed in the specification are not "essential" and need *not* be incorporated verbatim therein. Withdrawal of this objection is respectfully requested.

Finally, the examiner is thanked for indicating the typographical error in Example 2, at page 23. The requested correction has been made. Accordingly, withdrawal of all objections to the specification is requested.

Rejections under 35 U.S.C. §101

Claims 16 and 17 have been rejected under 35 U.S.C. §101. Is is respectfully submitted that reformatting of the method claims in this application for U.S. practice obviates this issue, and withdrawal of the rejection respectfully requested.

Rejections under 35 U.S.C. §112

Claims 16 and 17

Claims 16 and 17 have also been rejected under 35 U.S.C. §112, first paragraph. It is argued that "the invention is not supported by a specific and substantial utility." Claim 16 has been canceled for business reasons and to expedite prosecution. Claim 17 recites the treatment of various diseases, and thus does recite a specific and credible utility. Withdrawal of this rejection is respectfully requested.

Additionally, Claims 16 and 17 have been rejected under 35 U.S.C. §112, first paragraph, as it is argued that the specification does not "provide enablement for treating any human disease." In fact, the claims do not read on treatment of any disease, but on the specific diseases enumerated therein. The arguments in the Office Action pertaining to claims to "5-HT_{1A}-receptor related diseases" are moot, in view of the present scope of the claims. Withdrawal of this rejection is therefore also respectfully requested.

Finally, Claims 16 and 17 have been rejected under 35 U.S.C. §112, second paragraph. Cancellation of Claim 16, and clarification of Claim 17, also obviates this issue. Withdrawal of this rejection is thereof is respectfully requested.

Claims 1-14

Claims 1-14 have been rejected under 35 U.S.C. §112, first paragraph. It is argued that the specification does not enable making solvates. The thrust of the argument, for example, at page 6 of the Office Action, appears to be that solvates do not exist and

applicants somehow "will" them to be made. In fact, the production of solvates is well known in the art. The concern in the Office Action appears to be merely based on the breadth of the term "solvate," and the fear that some unspecified compound could not form a solvate. Such is insufficient to support an enablement rejection. In addition, the Office Action misstates the level of skill in the art. Even if the level of skill to practice the method claims were a physician with an MD degree (see for example, page 8 of the Office Action), the skilled artisan producing the compounds and compositions of the invention is a pharmaceutical chemist, well versed in the production of solvates and other pharmaceutical compositions.

It is well established that an unsupported suggestion that reactants within a class defined by claims in a typical method of use application would not work, or that such claims embrace inoperative members, insufficient basis alone for rejecting the claims. See *Ex parte Janin*, 209 USPQ. 761 (POBA 1979). In fact, it is clear that recitations in an Applicants' specification *must* be taken by the PTO as an assertion that all compounds encompassed in the claims are operative in the invention, in the absence of reasons or evidence to the contrary. *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971).

The first paragraph of 35 U.S.C §112 requires only *objective* enablement. Where a specification teaches the manner and process of making and using the invention, the specification *must* be taken as sufficient under §112, unless there is reason to doubt the truth of these statements. See *Marzocchi*, supra.

On the one hand, it is submitted that the Examiner has not provided any such reasons or evidence to doubt the assertion of the ability to produce solvates, as in the specification and, thus, the further steps of the analysis as set forth in *Marzocchi* are not reached. As clearly stated in *Marzocchi*, mere *breadth* of the claims does not, without more, result in non-enablement. As the court stated in *Marzocchi*:

> Turning specifically to the objections noted by the Board as indicated above, it appears that these comments indicate nothing more than a concern over the *breadth* of the disputed term. If we are correct, then the relevance of this concern escapes us. It has never been contended that Applicants, when they included the disputed terms in their specification, intended only to indicate a single compound. Accepting, therefore, that the term is a generic

> one, its recitation must be taken as an assertion by Applicants that all of the 'considerable number of compounds' which are included in the generic term would, as a class, be operative to produce the asserted enhancement of adhesion characteristics. The only relevant concern of the patent office under these circumstances should be over the *truth* of any such assertion. The first paragraph of §112 requires nothing more than *objective enablement*. How such a teaching is set forth, either by the use of illustrative examples or by broad term analogy, it is of no importance.

Marzocchi, supra. (Emphasis in original.) Thus, the concern expressed at pages 3 and 7 of the Office Action, apparently that the compounds used in the claimed methods are broad, does not provide the reasons or evidence necessary by *Marzocchi* to pass beyond the necessity merely for objective enablement.

With respect to the nature of the invention, in actuality, the nature of the invention is *not* complex, inasmuch as preparation of solvates is well established is well understood by one of skill in the art. Moreover, with respect to working examples, it is well established that working examples are *not* required to provide enablement. See, for example, *In re Borkowski*, 164 USPQ 642 (CCPA 1970

In conclusion, it is submitted that the *Wands* factors clearly do not result in undue experimentation in order to determine whether a given compound can produce a solvate. Thus, objective enablement is clearly present, and withdrawal of the rejection under 35 U.S.C §112 is respectfully requested.

Claims 1 and 9

Claims 1 and 9 have also been rejected under 35 U.S.C. §112, second paragraph. Reformatting of the claims in view of U.S. practice, with correction of the Markush language, obviates these issues. Reconsideration of this rejection is therefore respectfully requested.

The claims in the application are submitted to be in condition for allowance. However, if the examiner has any questions or comments, he is cordially invited to telephone the undersigned at the number below.

No fee is believed due with this response, however, the Commissioner is hereby

authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,
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Attorney Docket No.: MERCK-3071

Date: October 25, 2007

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